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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/082,673   | 02/22/2002  | Ronald Wetzel        | HME/7477.014        | 3069             |
| 29085  | 7590        | 10/19/2005           | EXAMINER            |                  |
| HOWARD EISENBERG, ESQ.<br>2206 APPLEWOOD COURT<br>PERKASIE, PA 18944 |             |                      | CHEU, CHANGHWA J    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |

1641

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                               |                               |  |
|------------------------------|-------------------------------|-------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/082,673 | Applicant(s)<br>WETZEL ET AL. |  |
|                              | Examiner<br>Jacob Cheu        | Art Unit<br>1641              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-26 and 50-53 is/are pending in the application.  
     4a) Of the above claim(s) 13-20 and 27-29 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 21-22, 24-26 and 50-53 is/are rejected.  
 7) ☒ Claim(s) 23 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's amendment filed on 8/12/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-12, 30-49 are cancelled.
2. Claims 21-26, 50-53 are under examination. Claims 13-20, 27-29 are withdrawn from further consideration.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 21-22, 24-26, 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Schezinger et al. (Cell Vol. 90, page 549).

Schezinger et al. teach constructing proteins containing polyglutamine repeats for study of neurodegeneration disease. The proteins constructed by Schezinger et al., for instance GST-HD51 (containing polyglutamine repeats) has dimensions of diameter of 6-7 nm and length less 100 nm or 60 nm (See Figure 4a). The other trypsin-treated filament has diameter of 7.7 nm and less than 100 nm (See Figure 4d; Note the arrow area where the length is less than 100 nm or 60 nm). Furthermore, Scheringer et al. also report that some filament “were randomly originated, 5-10 nm in diameter, and often measured up to 250 nm in length” (See Figure 6; page 552, right column, first paragraph)(emphasis added).

With respect to claim 26, Schezinger et al. teach using 20 polyglutamine repeats (See Experimental Procedure, page 556).

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With respect to claims 50-53, applicant recites process of making the product, i.e. freezing the solution containing peptides, incubating the frozen peptides to permit aggregates, sonication. The production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

### ***Response to Applicant's Arguments***

2. The rejections under 35 USC 102 (a) by Chen et al. (Protein Science (2001), Vol. 10, page 887-891) are withdrawn.

### ***Scherzinger et al. Reference***

3. Applicant argues that examiner's measurement on the dimensions of the filament, particularly in Figure 4, is not correct since applicant's own measurement shows that the dimension is about twice the length of the scale (See Figure 4, scale unit, 100 micron)(emphasis added). Applicant's arguments have been considered but are not persuasive.

As clearly set forth in this Office Action that Scherzinger et al. also disclose some of the filaments the dimension of 5-10 nm diameter, and up to 205 nm in length (page 552, right

column, first paragraph). Such features render claims 21-22 and 24-25 anticipated. Note, “up to” phrase denotes that the range of the length could be from 1-250 nm.

With respect to Figure 4, examiner acknowledges that the dimension of the individual filament might be difficult to measure as indicated by applicant (See Remarks, page 7, third paragraph). However, examiner would like to point out that Scherzinger et al. use enzymatic digestion method to isolate polyglutamine filament from cultured cells (See Method). The results of the enzymatic digestion generating various dimensions of filament, including diameter 10-12 nm and length from 100 nm up to several micrometers (See page 551, right column, second paragraph)(emphasis added). It is noted that such feature also anticipates the recited upper limit of the filament (See claim 21, diameter between 1-10 nm and a length between 20-100 nm). Assuming *arguendo* that Figure 4 cannot be precisely determined the dimensions, Scherzinger nevertheless still disclose that some random filaments (polyglutamine repeats) still contain the recited feature as in claims 21-22 and 24-25 (See above discussion; page 552, right column, first paragraph).

#### ***Allowable Subject Matter***

4. Claim 23 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
5. The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or suggests using a chemical synthesizing method to produce polyglutamine repeats filaments having diameter less than about 3 nm. The closest prior art is the reference of Scherzinger et al. where the filaments were isolated in vitro by GST-polyglutamine fusion protein from transfected E Coli. The filaments isolated from Sherzinger et al. have diameter from 5-10 nm (See Discussion above).

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### **Conclusion**

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner  
Art Unit 1641



October 12, 2005



LONG V. LE  
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10/15/05